PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 047956/311293	**FOR FURTHER ACTION**	See Form PCT/IPEA/416
International application No. PCT/US2006/018813	International filing date *(day/month/year)* 12.05.2006	Priority date *(day/month/year)* 13.05.2005
International Patent Classification (IPC) or national classification and IPC INV. A61F2/06		
Applicant Alveolus Inc.		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of a total of 6 sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising:
   a. ☒ *sent to the applicant and to the International Bureau)* a total of 3 sheets, as follows:
      ☒ sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).
      ☐ sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.
   b. ☐ *(sent to the International Bureau only)* a total of (indicate type and number of electronic carrier(s)) , containing a sequence listing and/or tables related thereto, in electronic form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).

4. This report contains indications relating to the following items:

☒	Box No. I	Basis of the report
☐	Box No. II	Priority
☐	Box No. III	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
☐	Box No. IV	Lack of unity of invention
☒	Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
☐	Box No. VI	Certain documents cited
☒	Box No. VII	Certain defects in the international application
☒	Box No. VIII	Certain observations on the international application

Date of submission of the demand	Date of completion of this report
2007-03-12	21.08.2007
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel. +31 70 340 - 2040 Tx: 31 651 epo nl Fax: +31 70 340 - 3016	Authorized officer Neumann, Elisabeth Telephone No. +31 70 340-3028

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.
PCT/US2006/018813

Box No. I Basis of the report

1. With regard to the **language**, this report is based on

   ☒ the international application in the language in which it was filed

   ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of:
   - ☐ international search (under Rules 12.3(a) and 23.1(b))
   - ☐ publication of the international application (under Rule 12.4(a))
   - ☐ international preliminary examination (under Rules 55.2(a) and/or 55.3(a))

2. With regard to the **elements*** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

Description, Pages	
1-12	as originally filed
Claims, Numbers	
1-23	as amended (together with any statement) under Art. 19 PCT
Drawings, Sheets	
1/5-5/5	as originally filed

   ☐ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing

3. ☐ The amendments have resulted in the cancellation of:
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
   - ☐ the description, pages
   - ☐ the claims, Nos.
   - ☐ the drawings, sheets/figs
   - ☐ the sequence listing *(specify)*:
   - ☐ any table(s) related to sequence listing *(specify)*:

* *If item 4 applies, some or all of these sheets may be marked "superseded."*

Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-23
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-23
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-23
	No:	Claims	

2. Citations and explanations (Rule 70.7):

see separate sheet

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following document:

D1: US 2001/025195 A1 (SHAOLIAN SAMUEL M ET AL) 27 September 2001 (2001-09-27)

The document D1 is regarded as being the closest prior art to the subject-matter of claim 1, and shows (the references in parentheses applying to this document):

An implantable device (96) for facilitating fluid flow between a branch of a bifurcated lumen and an interior region of the implantable device, the implantable device (96) comprising:
a scaffolding of struts (46) formed from a tube of memory material (nitinol, see paragraph 72) and having a proximal end and a distal end;
a cover (44) applied to and between the scaffolding of struts to define an interior region within the scaffolding (see paragraph 63); and
at least one drainage region having a proximal end, a distal end, and a plurality of drainage holes, namely two drainage holes (98,100) defined between the scaffolding (46) and through the cover (44) such that fluid is capable of flowing through the drainage holes, wherein the drainage region is offset from the proximal and distal ends of the scaffolding to facilitate fluid flow between the branch of the bifurcated lumen and the interior region of the scaffolding (see figure 16).

The subject-matter of claim 1 differs from this known document D1 in that the fluid is capable of flowing through the drainage holes irrespective of orientation of the scaffolding in relation to the bifurcated lumen which is also the problem to be solved (see also item VIII).

The subject-matter of claim 1 is therefore new (Article 33(2) PCT).
The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent method claim 14, which therefore is also considered new.

In document D1 the prosthesis has to be properly aligned both axially and rotationally, thereby requiring the ability to visualize both the axial and rotational position of the device (see § 106). The other documents cited in the search report either comprise a plurality of drainage holes which are arranged not about a circumference but in an axial direction (EP1472990 and WO03082153) and have to be aligned with the secondary lumens. WO-A-03065933 may comprise a plurality of drainage openings (see page 7, lines 17-21) but there is nothing disclosed about their position on the stent-graft. Moreover the side opening has to be properly aligned (see figure 5).

Therefore, the subject-matter of claims 1 and 14 involves an inventive step and meets the requirements of Article 33(3) PCT.

Dependent claims 2 - 13 and 15 - 23 specify advantageous embodiments of the subject-matter of claims 1 and 14 and fulfill the requirements of Articles 33(2), (3) and (4) PCT as well.

Re Item VII

1. Independent claims 1 and 14 are not in the two-part form in accordance with Rule 6.3(b) PCT, which in the present case would be appropriate, with those features known in combination from the prior art (document D1) being placed in the preamble (Rule 6.3(b)(I) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

2. The features of the claims are not provided with reference signs placed in parentheses (Rule 6.2(b) PCT).

3. Contrary to the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in the document D1 is not mentioned in the description, nor is this document identified therein.

Re Item VII

Claims 1 and 14 do not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claims attempt to define the subject-matter in terms of the result to be achieved (namely "the fluid is capable of flowing through the drainage holes irrespective of orientation of the scaffolding in relation to the bifurcated lumen"), which merely amounts to a statement of the underlying problem, without providing the technical features necessary for achieving this result.
The technical features which are disclosed in claims 1 and 14 are the plurality of drainage holes, for example two, which are arranged about a circumference of the scaffolding, for example at opposite sides (as it is the case in D1). It is not clear for the skilled person how the drainage holes should be arranged in order to achieve the desired result and to be distinguishable from the prior art (D1) in terms of technical features.

THAT WHICH IS CLAIMED:

1. An implantable device for facilitating fluid flow between a branch of a bifurcated lumen and an interior region of the implantable device, the implantable device comprising:

a scaffolding of struts formed from a tube of memory material and having a proximal end and a distal end;

a cover applied to and between the scaffolding of struts to define an interior region within the scaffolding; and

at least one drainage region having a proximal end, a distal end, and a plurality of drainage holes defined about a circumference of the scaffolding, between the scaffolding, and through the cover such that fluid is capable of flowing through the drainage holes irrespective of orientation of the scaffolding in relation to the bifurcated lumen, wherein the drainage region is offset from the proximal and distal ends of the scaffolding to facilitate fluid flow between the branch of the bifurcated lumen and the interior region of the scaffolding.

2. The implantable device according to Claim 1, wherein the scaffolding comprises a plurality of interconnected legs and connectors, and wherein the legs extend in circumferential rows about the implantable device, and the connectors extend longitudinally between adjacent rows.

3. The implantable device according to Claim 2, wherein the distal end of the drainage region is offset at least one row of legs from the distal end of the scaffolding.

4. The implantable device according to Claim 2, wherein each drainage hole is defined through the cover and between the legs and connectors.

5. The implantable device according to Claim 2, wherein each drainage hole is defined to substantially conform to one or more adjacent legs and connectors.

6. The implantable device according to Claim 1, wherein the distal end of the at least one drainage region is offset at least about 2 cm from the distal end of the scaffolding.

7. The implantable device according to Claim 1, wherein each drainage hole is circular or oval.

8. The implantable device according to Claim 1, further comprising a plurality of drainage regions, wherein each drainage region is configured to be positioned proximate to a respective branch of a bifurcated lumen.

9. The implantable device according to Claim 8, wherein the plurality of drainage regions are configured to be positioned proximate to at least one of a hepatic duct and a cystic duct of the biliary tract.

10. The implantable device according to Claim 1, wherein at least a portion of the implantable device between the proximal end of the scaffolding and the proximal end of the at least one drainage region is configured to be positioned adjacent to a target area located within a second branch of the bifurcated lumen.

11. The implantable device according to Claim 1, wherein the scaffolding comprises at least one radiopaque marker located proximate to at least one of the proximal and distal ends of the drainage region.

12. The implantable device according to Claim 11, wherein each radiopaque marker comprises an eyelet defined in the scaffolding.

13. The implantable device according to Claim 1, wherein the cover comprises a polymeric material.

14. A method for manufacturing an implantable device for facilitating fluid flow between a branch of a bifurcated lumen and an interior region of the implantable device, the method comprising:

forming a scaffolding from a tube of memory material having a proximal end and a distal end;

applying a cover to and between the scaffolding of struts to define an interior region within the scaffolding; and

defining at least one drainage region having a plurality of drainage holes defined about a circumference of the scaffolding, between the scaffolding, and through the cover such that fluid is capable of flowing through the drainage holes irrespective of orientation of the scaffolding in relation to the bifurcated lumen, wherein the drainage region is offset from the proximal and distal ends of the

scaffolding to facilitate fluid flow between the branch of the bifurcated lumen and the interior region of the implantable device.

15. The method according to Claim 14, wherein forming comprises etching a plurality of interconnected legs and connectors, and wherein the legs extend in circumferential rows about the implantable device, and the connectors extend longitudinally between adjacent rows.

16. The method according to Claim 15, wherein defining comprises defining a distal end of the drainage region at least one row of legs from the distal end of the scaffolding.

17. The method according to Claim 15, wherein defining comprises defining each drainage hole through the cover and between the legs and connectors.

18. The method according to Claim 15, wherein defining comprises defining each drainage hole to substantially conform to one or more adjacent legs and connectors.

19. The method according to Claim 14, wherein defining comprises defining a plurality of drainage regions.

20. The method according to Claim 14, wherein forming comprises forming at least one radiopaque marker proximate to at least one of a proximal end and a distal end of the drainage region.

21. The method according to Claim 14, wherein applying comprising dipping the scaffolding within a polymeric material.

22. The method according to Claim 14, wherein defining comprises penetrating the cover after applying the cover to the scaffolding to define each drainage hole.

23. The method according to Claim 14, wherein defining comprises masking at least a portion of the scaffolding during the applying step to define each drainage hole.